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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,545	11/15/2001	Herve Fridman	SF0941K	5775

7590 12/14/2006
Cynthia L Foulke
Patent Department K 6 1 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER

XIE, XIAOZHEN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/980,545	Applicant(s) FRIDMAN ET AL.	
	Examiner Xiaozhen Xie	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's amendment of the claims received on 27 September 2006 has been entered.

Claims 2 and 4-9 have been cancelled. Claims 1 and 3 are pending and under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

The rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's amendment and cancellation of the claims.

The rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to Applicant's amendment and cancellation of the claims.

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in response to Applicant's amendment of the claims.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Tartour et al., is withdrawn in response to Applicant's amendment of the claim.

The objection of claim 1 for reciting non-elected inventions is withdrawn in response to Applicant's amendment of the claim.

New Grounds of Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The amended claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartour et al., in view of WO 97/04097.

Applicant argues that neither Tartour nor WO 97/04097 teaches a method of suppressing metastatic tumor cell proliferation. Applicant argues that Tartour relates to the administration of an IL-17 antibody to nude mice into which cervical tumor cells had been implanted to form a primary tumor, and WO 97/04097 discusses inhibition of tumor growth and treatment of tumor and other conditions in which angiogenesis is involved, but WO 97/04097 is silent regarding treatment of metastatic tumors. Applicant argues that one of ordinary skill in the art would not have been motivated to combine the teachings in an attempt to obtain the claimed method.

Applicants' argument has been fully considered but has not been found to be persuasive.

It would appear that Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon

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references which made up the state of the art with regard to the claimed invention.

Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Tartour teaches that human cervical tumor cells that express IL-17, exhibited a significant increase in tumor size when transplanted in nude mice, and this growth promoting effect was abolished when an anti-IL-17 antibody was administered in nude mice. Even though Tartour does not use the term "metastatic tumor cell", it is well known in the art that such in vitro established cervical tumor cell lines are cancer cells, e.g., Hela, IC1. These cells inherently exhibit metastatic characteristics. Further, the instant claims are directed to suppressing tumor cell proliferation, not metastasis. The inhibition of tumor growth as shown in Tartour's studies is exactly the intended effect of the instant method. Tartour concludes that IL-17 is involved in the pathogenesis of human cervical tumor.

Tartour et al., however, does not teach administering the antibody to a human patient and using a monoclonal antibody that binds IL-17. WO 97/04097 compensates

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the deficiency by providing the teachings that monoclonal antibodies that bind to human CTLA-8 protein (IL-17) may be useful therapeutics for inhibition of tumor growth and treatment of tumor and other conditions in which angiogenesis is involved.

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine the teachings of Tartour, with those of WO 97/04097, to use an anti-IL-17 monoclonal antibody to inhibit cervical tumor cell proliferation in human patients afflicted with the disease. One of ordinary skill in the art would have been motivated to combine the teachings, because Tartour teaches an inhibitory effect of the anti-IL-17 antibody on human cervical tumor cell growth, and WO 97/04097 teaches such monoclonal antibodies and their usefulness in treating such tumors in humans. Therefore, the combined teachings provide a reasonable expectation of successfully treating cervical cancer in humans.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

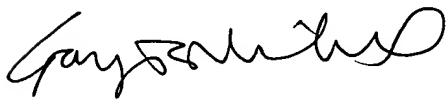
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
November 30, 2006



GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600